

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. EXAMINER INTERVIEW, CLAIM STATUS AND AMENDMENTS**

Claims 1, 5-7, 17, 19-21, 23 and 25-37 were pending in this application when last examined.

Claims 1, 5-7, 17, 19, 21 and 32 were examined on the merits and stand rejected.

Claim 20 was objected.

In item 7 on page 1, claims 26-31 and 33-37 were indicated as allowed. Applicants are grateful for the Examiner's indication of allowable subject matter.

Claims 23 and 25 were withdrawn as non-elected subject matter. It is respectfully requested that the withdrawn claims be rejoined with the elected invention upon allowance of the elected invention.

Applicants are grateful for the telephone discussions with Examiner Kam on April 20, 2006 and April 27, 2006, during which proposed claim amendments were discussed.

In particular, Applicants proposed amending the transformant of claim 1 to incorporate the subject matter of claims 6 and 7. It was argued that this amendment overcomes the remaining enablement rejection for the reasons discussed below.

Claim 1 has been so amended to incorporate the subject matter of claims 6 and 7. Support can be found in original claims 6 and 7.

Claims 6 and 7 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Withdrawn claim 23 has been amended to correct a minor grammatical error by removing an extra "the" before "peptide" in line 6. The claim has also been amended to delete "the steps of" in line 3. Support for these changes can be found in the claim as filed.

Withdrawn claim 25 has been amended to depend on claim 1 in view of the cancellation of claim 6. Claim 25 has also been amended to delete the formula for the substance PF1022

derivative, because the formula is now in amended claim 1 (from which claim 25 depends). The claim has also been amended to delete “the steps of” language in line 2. Support for these changes can be found in the claim as filed.

Claims 32 has been amended to depend on claim 1 in view of the cancellation of claim 6.

Claim 33 has been amended to add a period at the end of the claim.

No new matter has been added by this amendment to the claims.

Claims 1, 5, 17, 19-21, 23 and 25-37 are pending upon entry of this amendment.

During the interview, it was agreed that Mycelia sterilia remains an accurate generic designation for the PF1022 strain of the claims, even though the strain was also recently identified as Rosellenia necatrix. The Examiner acknowledged such in the Office Action of October 18, 2005 and the Miyadoh et al. reference (Nippon Kingakkai Kaiho, vol. 41, pp. 848-855 (2000)) attached thereto. It was agreed that there is no need to amend the claims and specification to reflect the recent identification of PF1022 strain as Rosellenia necatrix.

## **II. ADVISORY ACTION**

In item 5 on pages 1-2 of the Action, it is indicated that the last response has overcome the 112 second paragraph rejection, the 112 first paragraph written description and enablement rejections and the 102(b) rejection.

## **III. ENABLEMENT REJECTION**

In items 11 and 13 on page 2 of the Action, the Examiner has maintained the scope of enablement rejection of claims 1, 5-7, 17, 19, 21 and 32 under 35 U.S.C. § 112, first paragraph, on the basis that while the specification is enabling for transformants of Mycelia sterilia containing genes encoding SEQ ID NOS: 2, 4 and 6 that make para-substituted PF1022, wherein the substitution is a -NO<sub>2</sub> or -NH<sub>2</sub> functional group on the benzene ring, it is not enabling for any transformant to make a peptide or depsipeptide having a benzene ring substituted at para-position with a nitro or amino group using a gene encoding a modified sequence of SEQ ID NOS: 2, 4 or 6.

The rejection was maintained on the basis that independent claim 1 still encompasses transformants of an unspecified microorganism containing polynucleotides encoding the amino acid sequences of SEQ ID NOS: 2, 4 and 6 to produce an unspecified metabolite having a benzene ring substituted at para-position with a nitro group or an amino group. During the interview, the Examiner questioned whether organisms other than Mycelia sterilia could be transformed to produce the claimed transformant.

This rejection is respectfully traversed as applied to the amended claims.

The test of enablement is whether one reasonably skilled in the art could make or use the invention based on the disclosure in the specification coupled with the knowledge in the art without undue experimentation. See M.P.E.P. § 2164.01.

The amended claims no longer encompass transformants of an unspecified microorganism. Instead, the amended claims require that the microorganism to be transformed is a microorganism that produces PF1022. It is well established that microorganisms that produce PF1022 usually have a PF1022-synthesizing enzyme.

Furthermore, as disclosed on page 11, lines 1 to 26 of the disclosure, the following mechanism is involved in the production of a PF1022 derivative:

- (1) p-aminophenylpyruvic acid is produced in a transformant by introducing genes encoding the amino acid sequences of SEQ ID NOS: 2, 4 and 6;
- (2) D-phenyllactic acid dehydrogenase (D-PLDH) acts on the resulting product to produce p-amino-D-phenyllactic acid in the transformant;
- (3) the PF1022-synthesizing enzyme present in the microorganism acts on p-amino-D-phenyllactic acid; and
- (4) a PF1022 derivative is produced.

Based on this disclosure and the knowledge in the art, one skilled in the art could readily obtain the microorganism (which is to be transformed) that produces substance PF1022, and transform this microorganism by introducing SEQ ID NOS: 2, 4 and 6 into the microorganism to obtain the transformant that produces the PF1022 derivative. See the description of the various microorganisms at page 4 and in the Table on page 10.

The specification provides a description and working examples of such microorganisms and the resultant transformants. See for instance, the disclosure at pages 10-11, pages 19-20, Example 5 on pages 29-30 and Example 8 on page 34

Therefore, the microorganism and the transformant of amended claim 1 are described in the specification in such a way that those skilled in the art could carry out the invention without undue experimentation.

Therefore, in view of the above, the rejection of claims 1, 5-7, 17, 19, 21 and 32 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

#### **IV. INFORMATION DISCLOSURE STATEMENT**

Kindly return an Examiner-initialed copy of the PTO 1449 form submitted with the IDS of May 24, 2006.

#### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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